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(71) Applicant (for all designated States except US): **COOK
BIOTECH INCORPORATED [US/US]; 3055 Kent Av-
enue, West Lafayette, IN 47906 (US).**

(72) Inventors; and

(75) Inventors/Applicants (for US only): **OBERMILLER,**

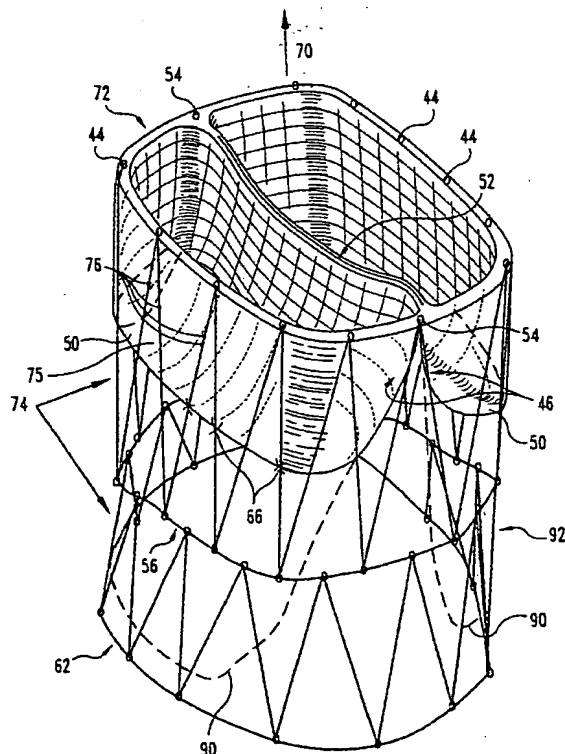
**Joseph, F. [US/US]; 3109 Courthouse Drive, Apt. 2A,
West Lafayette, IN 47906 (US). OSSE, Francisco, Jose
[BR/BR]; Rua Ferreira de Araujo, 496, Apartment 52,
CEP-05428001 São Paulo, SP (BR). THORPE, Patricia,
E. [US/US]; 10009 Fieldcrest Drive, Omaha, NE 68114
(US).**

(74) Agents: **GANDY, Kenneth, A. et al.; Woodard, Emhardt,
Naughton, Moriarty & McNett, Bank One Center/Tower,
Suite 3700, 111 Monument Circle, Indianapolis, IN 46204
(US).**

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[Continued on next page]

(54) Title: **STENT VALVES AND USES OF SAME**



(57) Abstract: The invention includes a medical device and more specifically relates to a valve found generally within a frame. In a preferred device, the frame preferably comprises a self-expanding stent frame, and the valve has at least one expandable and contractible pocket member within the stent frame for resisting and permitting fluid flow, respectively.

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STENT VALVES AND USES OF SAME

5

BackgroundTechnical field of the invention:

10

The invention includes a medical device and more specifically to a valve found generally within a frame.

In preferred devices the frame is comprised of a radially expandable stent which can be delivered
15 through a delivery device such as a catheter.

Background of the invention:

Lower extremity venous hypertension in addition to venous insufficiency is a major cause of morbidity in
20 the United States. Symptoms of venous disease include lower extremity edema, varicosities, skin pigmentation changes, skin ulceration, and general poor circulation.

One solution to this problem is to replace the defective valve or the vein with a valve assembly.

25 Current valves include a pressure responsive, pressure directed ball movement valve assemblies. The problem with mechanical ball valves is that mechanical valves are susceptible to clot formation. Additionally, there are problems associated with long-term wear and
30 tear on the device.

Artificial valves such as biological valves are also known. Biological valves include homografts, allografts, and xenografts. Problems associated with some biological valves include the supply of the

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valves, immunity response, or problems associated with matching the size with the donor.

Finally other problems associated with valve repair include placement problems in which the device
5 cannot be repositioned once it is ejected from the placement catheter, leakage that occurs around the valve, and emboli formation.

In light of this background, there remains a need for alternative and improved devices and methods for
10 providing valvular function within vessels of the body.

The present invention is addressed to these needs.

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Summary of the Invention

Disclosed is a medical device comprising a frame
5 that has a valve generally located within. In
preferred forms of the invention, the frame is
comprised of a radially-expandable stent (including
especially a self-expanding stent), which can be
delivered through a delivery device such as a catheter,
10 and then deployed and expanded at a target site in a
body lumen such as an artery or vein. For example, in
one preferred use, such a stent and method are used to
treat incompetent veins in the legs or feet.

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Brief Description of the Drawings

FIGs. 1A to 3 demonstrate one embodiment of the
5 invention comprising a stent.

FIGs. 4 to 8 demonstrate other embodiments of the
present invention comprising the valve.

FIGs. 9 to 11 demonstrate embodiments that
illustrate exemplary ways of attaching a plurality of
10 stents.

FIGs. 12 to 15 demonstrate exemplary embodiments
of the valve configuration in a variety of stent
embodiments.

FIG. 16 demonstrates one aspect of the invention
15 in situ.

FIGs. 17 to 19 demonstrate other alternative
embodiments.

FIG. 20 depicts a medical assembly of the
invention including a stent valve and a delivery device
20 for the stent valve.

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Detailed description of the invention

With reference to FIG. 15, shown is one embodiment of the present invention. The invention includes a frame such as a wire stent that has a lumen extending therethrough. Near one end of the stent is the valve assembly comprising some leaflets or cusps. A valve opening is generally located between the leaflets through which fluid flows. Although shown as a two leaflet valve, equally the invention can comprise, in any embodiment described herein, at least one leaflet such as two, three or four leaflets.

With respect to FIGs. 1A, 1B, and 1C, a frame is partially shown. The frame can comprise a stent 20. Choices of stent include a self expanding stent or a non-self expanding stent. In one embodiment of the present invention stent 20 is a self expanding stent such as the Gianturco stent available from Cook Inc. of Bloomington, IN as described in U.S. patent 4,580,568, the entire disclosure of which is expressly incorporated by reference herein. Such stent can be any length, but in one embodiment, the stent is about 15 mm long. Stent 20 includes a plurality of bends 22, which generally form the area in which the stent struts 24 reverses direction. Bends 22 are generally rounded to provide an atraumatic condition. Since the stent 20 is generally located in a vessel or body lumen of some type, the stent 20 can be cylindrical and therefore has a stent diameter 21 (shown in FIG. 3). In another embodiment, the stent 20 can also have a plurality of connectors 26 that connect adjacent struts 24. One way to provide a connector 26 is to dispose a solder

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bead between the adjacent struts. However connector 26 can also be a suture, weld, adhesive, rod, clamp, or other well-known ways to connect adjacent struts 24. Connector 26 provides several non-critical advantages.

5 Connectors 26 can attach adjacent struts 24 to minimize or prevent flaring of the ends of the stent 20. Furthermore, connector 26, if placed near the bend 22, can create a hole 28 wherein the boundaries of the hole are the wires of the stent operating in general.
10 conjunction with the connector 26. This creates a hole 28 through which a thread or suture can run. However, as shown in FIG. 1C, a separate prefabricated hole can be created by separately attaching a hole assembly, such as a cap 29 over the bend 22. In any case, one
15 benefit of the connector 26 or cap 29 is that they increase the radiographic visualization of the invention. Particularly, if the connector 26 is a solder bead, it has increased radiopacity.

With respect to FIGs. 2A and 2B, shown is part of
20 the stent in which connector 26 attaches adjacent struts 24. As mentioned above, a thread or suture can be threaded through the hole 28. A proximal suture 30 can be sewn through the stent proximal bends 22 or stent proximal ends 31 of the stent. Similarly, a
25 distal suture 32 can be sewn through the stent distal end 33 or the stent distal bends 22 of the stent. One way to thread the suture is shown in FIG. 2B wherein the suture 35 (generically any suture) runs over the strut 24 to enter the hole 28, through hole 28 to come
30 behind the same strut 24, over the strut 24 and across to the adjacent strut 24 running over the adjacent strut 24, behind the adjacent strut 24 to come from

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behind and through hole 28, and then run subsequently over adjacent strut 24. Once the struts are connected via the suture, the suture can be pulled to a predetermined tightness to control the overall stent size. Accordingly, the stent can be so constructed to have a predetermined stent perimeter 34. To this end, the stent lumen 36 will also have an appropriate size.

The stent can be constructed so as to have a different perimeter length at the proximal or distal ends.

10 With regard to FIG. 3, shown is a cylindrical stent 20 that has the proximal and distal sutures running through the bends 22 or holes 28 of the proximal and distal ends of the stent. By altering the tautness of the sutures, the size of the stent lumen 15 36, the stent diameter 86, and the stent perimeters 34, can be adjusted. As can be seen, distal perimeter suture 32 runs along the stent distal end 33, whereas proximal perimeter suture 30 runs along the stent proximal end 31. The respective sutures run through 20 hole 28 of each bend 22.

With respect to FIGs. 4 and 5, the valve material 38 is shown, in this exemplary embodiment, as a sheet.

In so constructing the valve 41, the valve material 38 is draped across the stent lumen 36 opening (such as 25 shown on the proximal portion of the stent) and then pushed down into the stent lumen 36 itself. Excess material can be kept outside the stent, which will later become a potential fold-over 42. However, the excess material can also be trimmed off. The valve 30 material 38 is connected to the stent, using for example, distal valve-stent suture 40. However, any well known ways to connect the valve to the stent is

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contemplated, such as but not limited to, sutures, adhesives, folds, or the like. In one embodiment shown in FIG. 5, the valve-stent suture 40 can share the hole 28 with distal suture 32 near the stent perimeter 34.

5 The valve material 38 can be any biocompatible material such as polyethylene terephthalate (PET), polypropylene (PP), polytetrafluorethylene (PTFE), or any polymer or derivative thereof, and also includes commercially known materials such as GORE-TEX, DACRON,
10 or any other synthetic material. The preferred material 38 will be advantageously compliant and employed so as to permit effective valve function as described herein and in the case of
15 collapsible/expandable state devices will retain integrity and function when cycled between these states.

 It is preferred to use a biomaterial that serves as a biocompatible scaffold with the ability to remodel host tissue. Accordingly, a naturally occurring
20 biomaterial is highly desirable. One such biomaterial is collagen and more particularly, a collagen based biomaterial called extracellular matrix (ECM). Examples of ECM's include pericardium, stomach submucosa, liver basement membrane, urinary bladder
25 submucosa, tissue mucosa, dura mater, and small intestine submucosa. One such biomaterial is the ECM, such as submucosa, and more particularly is small intestine submucosa (SIS). SIS can be made in the fashion described in Badylak et al., US Patent
30 4,902,508; Intestinal Collagen Layer described in US Patent 5,733,337 to Carr and in 17 Nature Biotechnology 1083 (Nov. 1999); Cook et al., WIPO Publication WO

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98/22158, dated 28 May 1998, which is the published application of PCT/US97/14855; Gastric Submucosa as described in WO 98/26291 (PCT/US97/22729), claiming priority to US Provisional application 60/032,686;
5 Liver tissue as described in WO 98/25637 (PCT/US97/22727), claiming priority to 60/032,680; Stomach Submucosa as described in WO 98/25636 (PCT/US97/23010), claiming priority to 60/032,683; and Urinary Bladder Submucosa as described in US Patent
10 5,554,389; all the disclosures of which are hereby expressly incorporated by reference. Irrespective of the origin of the valve material (synthetic versus naturally occurring), the valve material can be made thicker by making multilaminate constructs, for example
15 SIS constructs as described in US Patents 5,968,096; 5,955,110; 5,885,619; and 5,711,969; the disclosures of which are entirely and expressly incorporated by reference.

With respect to FIGs. 6A and 6B, shown is the
20 connection of the valve to the stent frame. As described above, the valve can be sutured at the distal portion of the stent using distal valve-stent suture 40. Similarly, the proximal portion of the valve can be sutured to proximal portion of the stent, and more
25 particularly to proximal perimeter suture 30. Shown is the valve connected to the proximal portion of the stent at proximal valve-stent suture 44. Suture 44 can be through a bend 22 or can attach to the proximal perimeter suture 30. In a traditional Gianturco Z-
30 stent, it is either an 8 (bend) point or 10 (bend) point stent, so one leaflet of the valve can be sutured to the four points of an 8 point stent thereby

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comprising one half of the stent. To provide further integrity, the valve can be sutured at the proximal and distal end to the perimeter sutures themselves, without actually being sutured to any or all of the stent bends 22.

5 With respect to FIG. 6B, shown is the valve with the stent frame removed. Once the sutures are generally in place, the valve sheet 38 will form a valve pocket 46, extending inside the stent lumen in
10 which the fluid will fill. Proximal valve perimeter 48 will have the sutures connecting the valve to the stent (not shown). Once the distal sutures are in place, the general shape will likely resemble a pocket with the pocket having a valve apex 50. There is a part of the
15 valve that will form central valve portion 49 that is not directly sutured to the stent. This valve portion 49 will form the valve opening 52 through which fluid will pass. Thus, upon filling of the valve pocket 46, the fluid pressure will exert outwards causing valve
20 portion 49 to extend outward. When it does, it will contact the other leaflets or cusps and form a seal to stop or impede fluid flow.

FIG. 7 shows a top view of the stent valve. In this particular non-limiting view, shown is the valve
25 opening 52 in a slightly open configuration. Valve pockets 46 are shown in a slightly distended configuration. The valve is connected, for example, by sutures to the stent perimeter 34 and also forms a valve perimeter 48. Because of the opening and closing
30 of the valve, there may be increased wear and tear at the valve-stent-opening connection. At this point, one embodiment of the present invention provides a

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reinforcement at this point. For example, this reinforcement can be a plurality of reinforcement sutures 54, adhesive, another material, or any other mechanism that permits increased structural integrity.

5 FIG. 8 demonstrates a view of the stent valve once the distal portion of the valve is sewn to a distal bend 22 and also shows the proximal portion of the valve being connected to the proximal portion of the frame with one suture in the foreground, one suture in
10 the background. In addition, the reinforcement suture 54 is found in the foreground. Although only two sutures 44 are seen at the proximal portion, it is of course well-understood that some or each of the proximal bend of the frame can be connected to the
15 proximal portion of the valve. Similarly, although only one distal suture 40 is shown, there may be as many distal sutures necessary to connect the valve apex 50 or the distal portion of the valve to the frame. It is well understood that this may be just one distal
20 suture or many distal sutures. Varying the number of distal sutures will vary the shape, tightness, and overall configuration of the valve, valve pocket 46, and the valve apex 50.

25 The valve opening 52 although already described above, is actually created in the final step of preparation of the preferred device manufacture. The construction mentioned above would be repeated on the other side of the valve to create the valve pocket 46, valve apex 50, and the like on the other side. At this
30 point, though, there is no valve opening 52. The valve opening 52 is created by creating a slit in the sheet to create the opening. The slit can be sized according

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to the intended flow rate of the passing fluid. Accordingly, a large slit would create a large valve opening or orifice and permits a large volume of fluid to pass therethrough. The slit can be created by poking
5 a scalpel through it and running it to the desired length. However, due to potential fatigue at the orifice, another set of reinforcements may be added to the orifice perimeter. Therefore, as shown in FIGS. 7 and 8, an orifice reinforcement 53 may be created by
10 any known conventional ways, such as sutures (resorbable or non-resorbable), adhesive, string, staples, rings, or the like.

Therefore, the stent valve as constructed can be using one stent with the valve material enclosed
15 therein. Of course in the single stent configuration, the overall length can be adjusted by elongating the length of the struts 24. However, devices of the invention can be built using a plurality of stents to elongate the overall size of the stent, if desired. In
20 this regard, it will be preferred that the length of the device 20 is sufficient to provide an aspect ratio (length to expanded diameter) sufficiently high to facilitate proper alignment of the device 20 within the vessel, with the axis of the device lumen generally
25 aligned with the axis of the vessel. For example, devices having a ratio of length:expanded diameter of 1:1 or greater, or about 2:1 or greater, will be preferred. It will be understood that while such dimensions will advantageously facilitate placement of
30 the inventive devices, they are not necessary to the broader aspects of the invention.

With reference to FIG. 15, shown is a double stent

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structure with the valve. Returning now to FIG. 9, shown is a first stent 58 and a second stent 60. For the purposes of discussion only, first stent 58 is shown to be atop of the second stent 60. Ultimately as shown herein by way of example only, the valve will reside in the first stent 58. It should be noted however that the valve can reside in the second stent 60 also as shown in FIG. 17. Furthermore, the overall length can be increased by joining several stent valves together as shown in FIGs. 18 and 19, thereby having a plurality of stents, such as a first stent 58, second stent 60, and a third stent 61. The valve 41 can be placed in any or all stents, in any combination, for example, as shown by the dotted lines. In this regard, it is suggested and intended that many stents can be joined and that each or any stent may house a valve or plurality of valves. One benefit of having a plurality of stents is that upon ejection of the placement device, the invention will provide a self-aligning feature in the vessel. This is because the plurality of stents is generally longer with respect to the stent diameter, or the plurality of valve device(s), as discussed above.

Manufacture of the multi-stent or multi-valve device will generally follow the same construction as described above. The same considerations in making a single valve single stent device applies equally to the elongated device.

Returning now to FIGs. 9 and 10, shown are methods of connecting the first stent 58 and second stent 60. Equally, the construction shown from now on also includes construction of at least two stents or at

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least two valves. First stent 58 and second stent 60 has bends 22 that are adjacent each other. Shown in FIG. 9 is where the first stent 58 has its bends beside the bends of the second stent 60 such that they are not touching each other (although they may touch). They are connected together in the manner described above, and for example by stent-stent suture 56. Stent-stent suture 56 can be resorbable or non-resorbable. This suture travels through the distal bends of the first stent 56 and the proximal bends of the second stent 60.

The suturing pattern can be that described in FIG. 2B and the accompanying discussion. As shown in FIG. 10, the bends can be juxtaposed over each other to provide an overlap such that the stent-stent suture 56 will go through the bends at the same time. Therefore, the construction contemplates that the stent bends may touch, overlap, or not at all.

FIG. 11 shows one embodiment of the present invention in which the valve apex 50 is sutured to at least three bends: two bends of the first stent 56 and one bend of the second stent 60. In this regard, the valve also operates to keep the first stent 56 partially connected to the second stent 60. From the bends, a plurality of valve apex sutures 66 are seen. These sutures can emanate from the bends and each bend can have many valve apex sutures 66 that travel in many directions. Using multiple valve apex sutures 66 that emanate in many directions and using a plurality of bends (from either stent), generally functions to minimize any parachuting or inversion of the valve pocket 46.

FIG. 12 demonstrates a top view of the multi-stent

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device in which the valve opening 52 is seen (in a closed position) and the valve pocket 46 and valve apex 50 is connected to three bends. Again it should be understood that many sutures may emanate from many
5 bends from any stent.

As described earlier, the excess material can either be trimmed off or folded over the outer surface of the device. Shown in FIGs. 13A and 13B, is the excess material being folded over the device and
10 attached at the distal end of the first stent 58. Shown in dotted lines is the first stent 58. FIG. 13B shows that the fold-over 42 provides a second material outer sheath so that the suture passes through the inside and outside material to increase structural
15 integrity. Also, by folding over the excess material, a smoother surface is presented rather than the naked frame of the tip of the bend.

In all embodiments of the invention, the external surface of the frame can be covered with a sheath that
20 is not necessarily the same material as the valve 41. For example, while the valve can be a naturally occurring material, the outer sheath can be synthetic material such as described herein. The sheath, therefore, can be the fold-over of the valve material,
25 another type of naturally occurring material, or a synthetic material. Accordingly, the sheath may partially or totally cover the frame.

FIG. 14 shows an embodiment in which both the first stent 58 and second stent 60 are covered by the
30 fold over 42. Here, the fold-over 42 is connected to the distal portion of the second stent 60. In this manner, the entire device may be covered with an outer

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sheath of biomaterial. The benefit of doing so, especially if using SIS or other similar ECMs, is that the regrowth and endothelialization of the device embeds and encapsulates the frame. Accordingly, there
5 is a reduced risk of device migration. Furthermore, due to the remarkable remodeling properties of SIS, the outer SIS sheath acts as a conduit for host tissue to infiltrate the device and remodel the valve itself. Over the course of months, the valves are replaced by
10 host tissue and the SIS disappears.

FIG. 15 shows yet another embodiment of the present invention. In this demonstration, the valve is located in the first stent 58, sutured at the proximal end at the stent perimeter. The valve apex 50 is sewn
15 somewhat proximal of the stent-stent suture 56. The valve apex 50 is sewn at the valve apex sutures 66 to an intermediate portion of the frame. To minimize parachuting or inversion, a valve intermediate portion 75 may be sutured using valve intermediate suture 76 to
20 connect the valve to the frame. In addition, the valve may be so constructed to extend the valve's length to create an elongated valve pocket 90 (shown by the dotted lines). While the extended pocket 90 can be connected to the distal perimeter of the second stent
25 distal suture 62, it can also be connected to an intermediate portion of the second stent.

With further reference to FIG. 15, it is seen that the valve opening 52 is a slit that extends across the first stent diameter 21 but terminates several
30 millimeters before reaching the edge. In some embodiments, this distance could be 1-5 mm from the edge. Of course, it is understood that the invention

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contemplates any distance that varies the length of the slit. Also, shown in FIG. 15, but equally applies to any device described herein, is an anchor 92, which can be anchor barbs 92. These barbs 92 can dig into the
5 adjacent vessel wall to relatively affix the device at its location. Anchor 92, although shown as barbs, may include hooks, adhesives, knobs, a textured surface, or any other treated surface that facilitates relative affixation of the device in its location. Similarly,
10 the outer surface of the fold-over or sheath can be so configured to provide anchoring.

FIG. 16 demonstrates the device upon implantation into the patient. Upon implantation the device generally resides in a vessel 80. For example, the
15 vessel could be vein, artery or the heart or wherever a valve is necessary. In one preferred use, the vessel is an incompetent vein in the leg or foot of a patient.

The device 20 reduces or prevents retrograde blood flow, while normal blood flow is permitted to travel
20 through device 20. Illustrative veins in which the device 20 may be used include, for example, saphenous veins, femoral veins, popliteal veins, tibial veins, and the inferior vena cava.

The vessel 80 has an inner luminal surface 82 in
25 which the fluid flows. The fluid flow path is shown as fluid path 70. Vessel 80 also has a vessel diameter 84. The medical device, upon implantation, will also have a device outer stent diameter 86. The outer diameter 86 will be chosen to permit contact with the
30 inner luminal surface 82. The optimized fit will decrease the leakage around the device by contacting the inner luminal surface 82. A tight fit can be

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accomplished by sizing the stent diameter to be greater than the vessel diameter. For example, a stent diameter that is about 110 percent greater than (i.e. 1.1 times) the vessel diameter provides a good fit. Expanded
5 stent diameters of about 10 mm to about 30 mm will be typical in many applications of the present invention.

Again, while it is shown in this FIG. 16 that the valve is located in the first stent 58 and only the first stent 58 is covered by the fold-over 42 or
10 sheath, it should be remembered that the valve could be located in the second stent 60. Similarly, the fold-over 42 or sheath could extend onto the second stent 60.

The standard method of deploying the medical
15 device 20 in a vessel 80 involves the use of a medical assembly (see FIG. 20) including the device 20 and a delivery device such as a percutaneous delivery device, e.g. a catheter 100. The frame is configured to a contracted state, e.g. by resiliently forming the frame
20 into a contracted configuration, to load into the delivery device (catheter). The catheter can be introduced into the patient via a suitable approach, for example through the jugular or femoral vein. To advance and deploy the device from the distal end of
25 the delivery catheter, a pusher 101 is placed into the catheter lumen. When the device 20 is fully deployed, it assumes the second, expanded configuration within the vessel 80 as depicted in FIG. 16. The stent frame, being made of resilient material, conforms to the shape
30 of the vessel wall such that when viewed on end, the device 20 has a circular appearance when deployed in a round vessel.

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FIGs. 17, 18, and 19 show other described embodiments. FIG. 17 demonstrates the valve 41 in the second stent 60. In this embodiment, the valve apex 50 is connected to the second stent's distal perimeter.

5 FIG. 18 demonstrates at least two stent frames connected together. In this particular embodiment, the valve is located in the first stent 58; with the valve apex 50 being connected at the first stent 58-second stent 60 junction. In dotted lines, however, there may

10 be many stents, such as first stent 58, second stent 60, and third stent 61. The valve 41 may be found in any of the stents or in all. Similarly, in the three stent configuration, the valve may begin at the first stent and have the valve apex 50 be generally located

15 in the third stent 61. FIG. 19 shows another embodiment of the present invention in which the valve 41 begins in the second stent 60 and extends into the third stent 61 thereby having the first stent 58 being empty.

20 Finally, since the device is located in an *in vivo* environment, the device may be treated with therapeutic agents to facilitate healing. For example, the frame may be treated with therapeutic agents such as anti-cancer drugs, plaque busters, anti-coagulants, or the

25 like. Similarly, the valve material can be treated with therapeutics agents such as anti-cancer drugs, plaque busters, anti-coagulants, proteins, growth factors, proteoglycans, and the like. Furthermore, radiopaque agents may be added, such as tantalum, barium, bismuth,

30 or the like to increase radiopacity. These ingredients can be bonded to the frame or the valve material such as rubbing the agent in, bonding it, adhering it, or

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the like.

While the invention has been illustrated and described in detail in the drawings and the foregoing text, it is understood that these are only some
5 embodiments and that the scope of the invention is not solely defined by the description herein but also by the appended claims. All modifications and changes that come within the spirit of the invention are hereby
10 protected.

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What is claimed is:

1. A stent valve, suitable for placement in a vessel, the vessel further having a diameter and an
5 inner lumenal surface, comprising:
 - a) a stent having a diameter, a proximal end, and a distal end; the stent sized to permit contact with the inner lumenal surface of the vessel;
 - b) a valve having a proximal end and a distal end,
10 the valve being at least partially located within an inner portion of the stent, wherein the valve comprises a biocompatible material.
2. The stent valve of claim 1, wherein the stent
15 is a self-expanding stent.
3. The stent valve of claim 1, wherein a sheath partially covers the stent.
- 20 4. The stent valve of claim 3, wherein the sheath further comprises substantially biocompatible material.
5. The stent valve of claim 4, wherein the stent
25 is a self-expanding stent.
6. The stent valve of claim 1, wherein the stent has a diameter greater than the vessel diameter.
- 30 7. The stent valve of claim 6, wherein the stent has a diameter 110 percent greater than the vessel diameter.

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8. The stent valve of claim 6, wherein a sheath partially covers the stent.

5 9. The stent valve of claim 8, wherein the sheath comprises a biological material.

10 10. The stent valve of claim 9, wherein the sheath comprises tissue submucosa.

15 11. The stent valve of claim 10, wherein the submucosa further comprises at least one of a gastric, liver, intestinal, urinary, stomach, and genito-urinary tissue.

20 12. The stent valve of claim 1, wherein the valve further comprises at least one leaflet, wherein the at least one leaflet is capable of preventing a backflow of blood.

25 13. The stent valve of claim 1, wherein the valve proximal end is connected to the stent proximal end.

30 14. The stent valve of claim 13, wherein the valve proximal end is sutured to the stent proximal end.

35 15. The stent valve of claim 13, wherein the valve proximal end is sutured at least 4 times to the stent proximal end.

40 16. The stent valve of claim 13, wherein the

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valve proximal end is sutured at least 7 times to the stent proximal end.

17. The stent valve of claim 1, wherein the valve
5 distal end is connected to the stent distal end.

18. The stent valve of claim 1, wherein the valve distal end is sutured to the stent distal end.

10 19. The stent valve of claim 18, wherein the valve distal end is sutured at least 2 times to the stent distal end.

15 20. The stent valve of claim 18, wherein the valve distal end is sutured at least 3 times to the stent distal end.

20 21. The stent valve of claim 1, wherein an intermediate portion of the valve is connected to an intermediate portion of the stent.

22. The stent valve of claim 1, wherein an intermediate portion of the valve is connected to the stent distal end.

25 23. The stent valve of claim 1, wherein a valve opening extends substantially across the stent diameter.

30 24. The stent valve of claim 23, wherein the valve opening terminates at least 1 mm from a stent perimeter.

- 24 -

25. The stent valve of claim 23, wherein a
reinforcement
is generally located at a valve opening and a stent
5 perimeter.

26. The stent valve of claim 1, wherein said
stent is a
radially expandable stent, said radially expandable
10 stent having a first configuration adapted for delivery
through a lumen of a delivery device, and a second
configuration for conforming to an interior wall of a
body vessel.

27. The stent device of claim 26, wherein the
15 body vessel
is a vein.

28. A medical device, suitable for placement in a
vessel,
20 the vessel further having a diameter and an inner
luminal surface, comprising:

- a) at least one stent, the at least one stent
having a proximal end, a distal end, and a lumen
extending therethrough;
- 25 b) a valve having a proximal end and a distal end,
the valve generally located within the lumen of the at
least one stent;
- c) the valve distal end being secured to an
intermediate portion of the at least one stent; and
- 30 d) the valve further comprising a biological
material.

- 25 -

29. A medical device, suitable for placement in a vessel, the vessel further having a diameter and an inner luminal surface, comprising:

- 5 a) at least one stent, the at least one stent having a proximal end, a distal end, and a lumen extending therethrough;
- b) a valve having a proximal end and a distal end, the valve generally located within the lumen of the at least one stent;
- 10 c) the valve distal end being secured to an intermediate portion of the at least one stent; and
- d) the valve further having a valve opening, the valve opening also further comprising a reinforcement disposed on the valve opening.

15

30. A medical device, suitable for placement in a vessel, the vessel further having a diameter and an inner luminal surface, comprising:

- 20 a) at least one stent, the at least one stent having a proximal end, a distal end, and a lumen extending therethrough;
- b) at least one valve having a proximal end and a distal end, the valve generally located within the lumen of the at least one stent
- 25 c) the at least one valve distal end being partially secured to an inner portion of the at least one stent; and
- d) the valve further comprising a biological material.

30

31. A radially-expandable stent valve device for placement in a body vessel, comprising:

- 26 -

a self-expanding stent frame, said self-expanding stent frame conformable to a first, contracted state adapted for delivery through a lumen of a delivery device, and a second, expanded state for conforming a
5 lumen of the vessel;

a valve attached to said frame and functional to resist fluid flow in a first direction through said stent frame and permit fluid flow in a second direction through said stent frame opposite said first direction;

10 said valve comprising a compliant biocompatible material defining at least one pocket member within said frame, said pocket member having an opening for receiving fluid flowing in said first direction and adapted to thereupon expand, said pocket member further
15 adapted to contract upon impingement with fluid flowing in said second direction; and

said biocompatible material sufficiently compliant and said pocket member defined wherein said valve remains functional after contraction of said stent
20 frame to said first, contracted state and expansion of said stent frame to said second, expanded state.

32. The stent valve device of claim 31, wherein said valve comprises at least two of said pocket
25 members.

33. A medical assembly, comprising a stent valve device of any of claims 2, 5, 26 and 29 received within a lumen of a delivery device.

30

34. A method for providing a valve in a body lumen, comprising:

- 27 -

providing a delivery device having a lumen having received therein a stent valve device of any of claims 2, 5, 26 and 29;

5 deploying said stent valve device from said delivery device within said body lumen.

35. The method of claim 34, wherein said body lumen is a venous lumen.

10 36. The method of claim 35, wherein said venous lumen is within a vein selected from a saphenous vein, a popliteal vein, a femoral vein, a tibial vein, and the inferior vena cava.

15

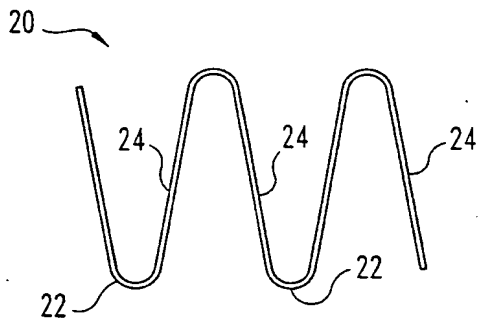


Fig. 1A

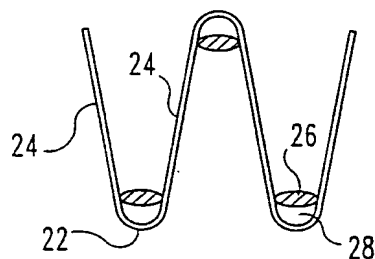


Fig. 1B

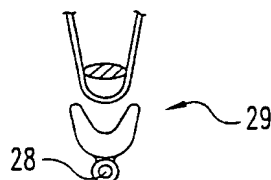


Fig. 1C

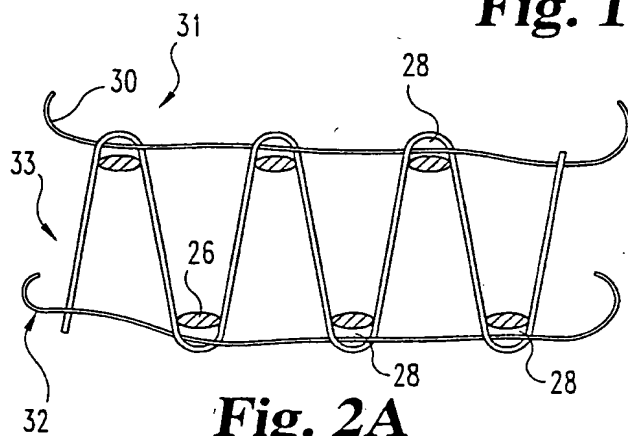


Fig. 2A

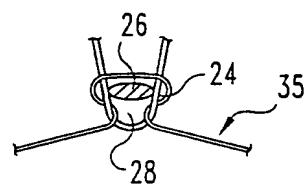


Fig. 2B

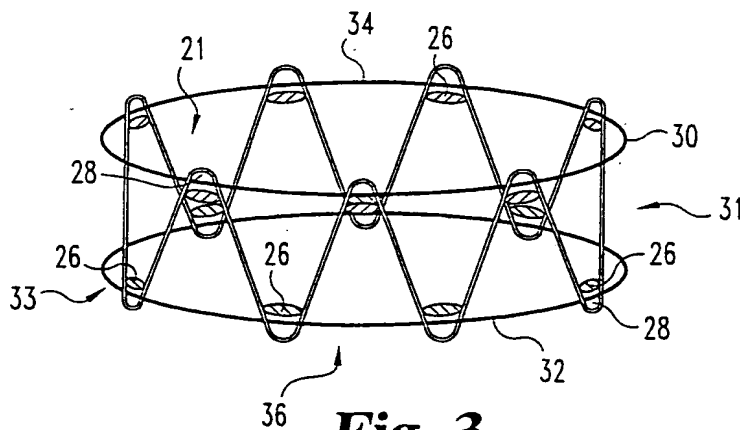


Fig. 3

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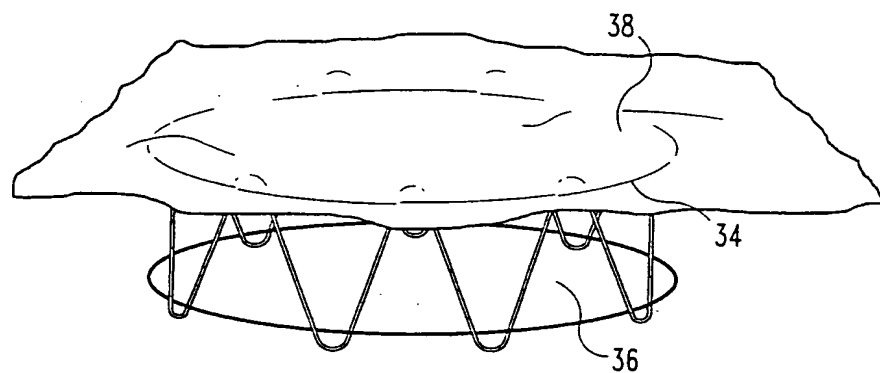


Fig. 4

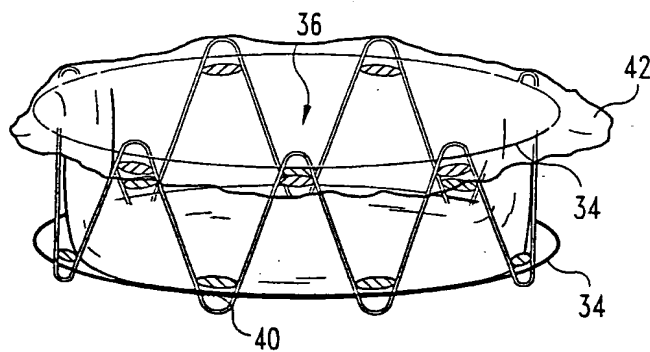


Fig. 5

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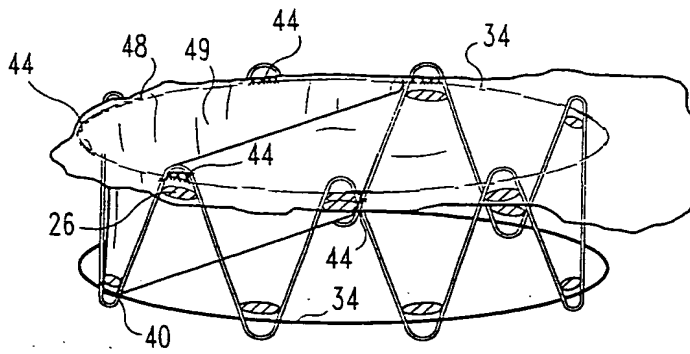


Fig. 6A

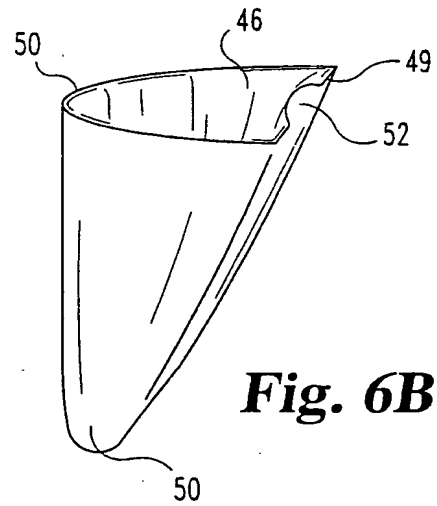


Fig. 6B

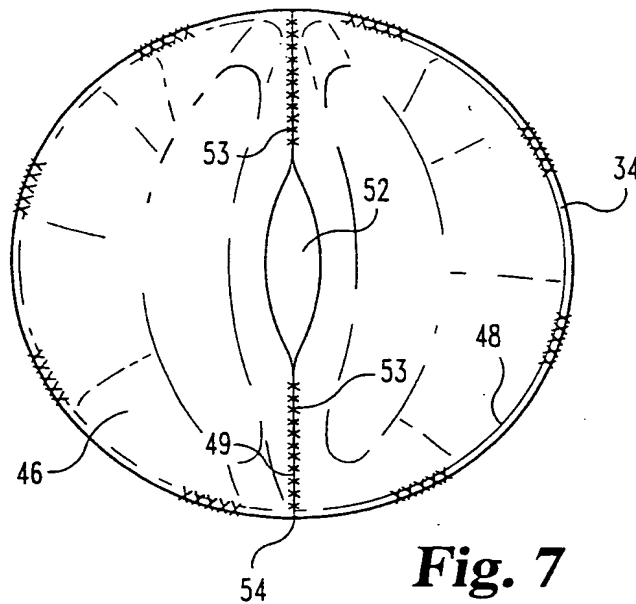


Fig. 7

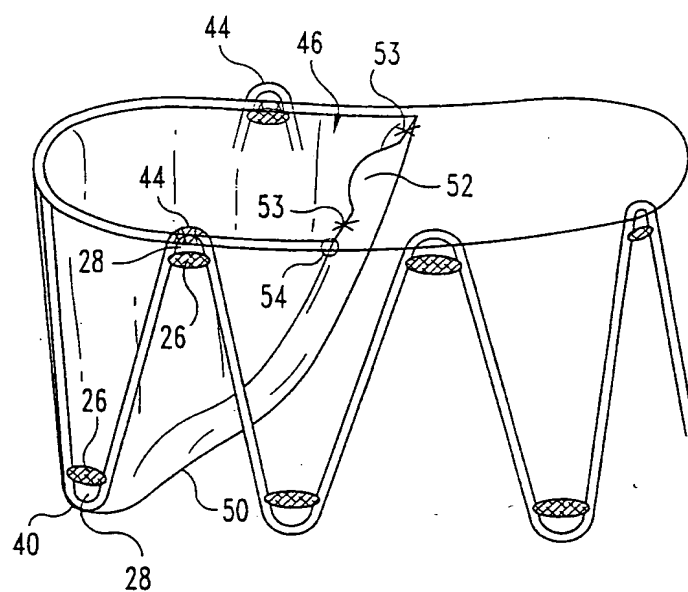


Fig. 8

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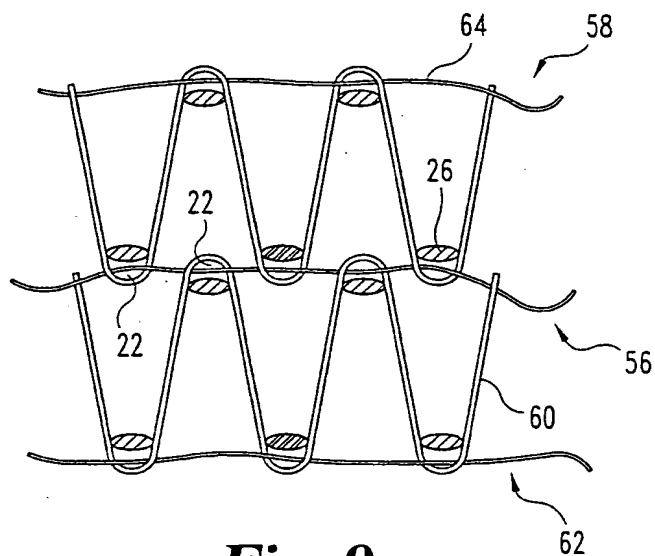


Fig. 9

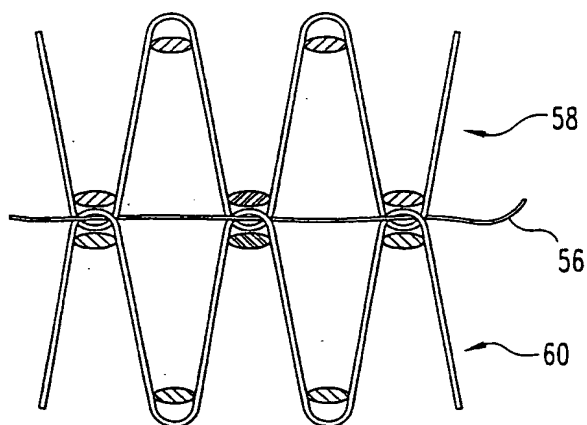


Fig. 10

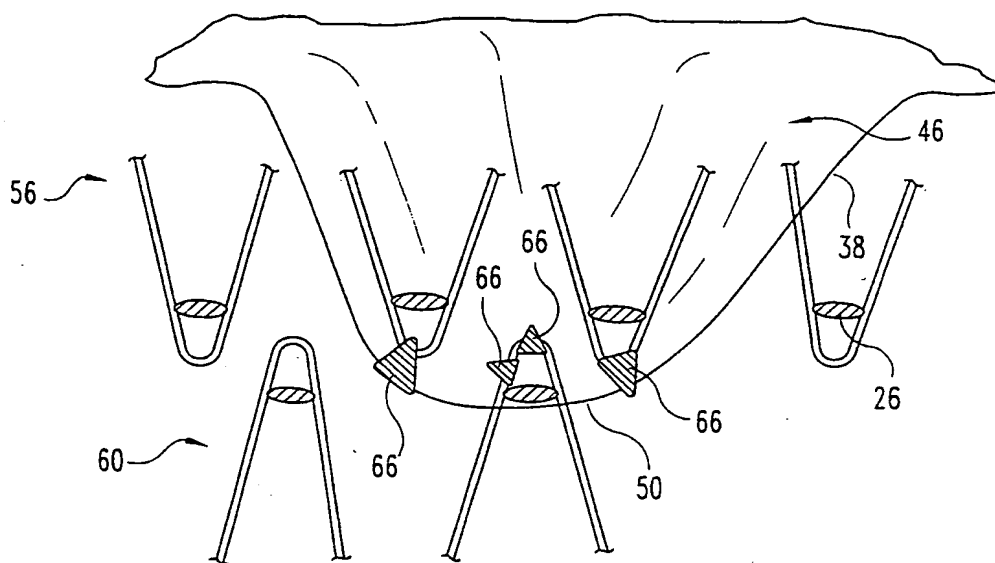


Fig. 11

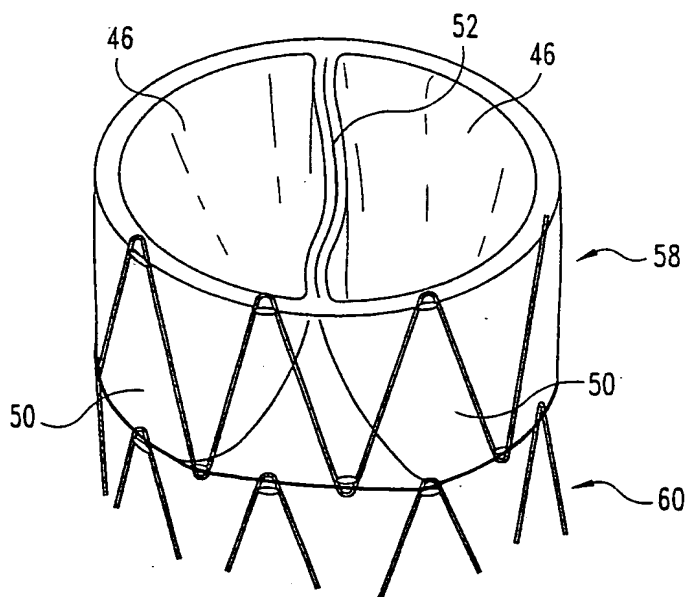


Fig. 12

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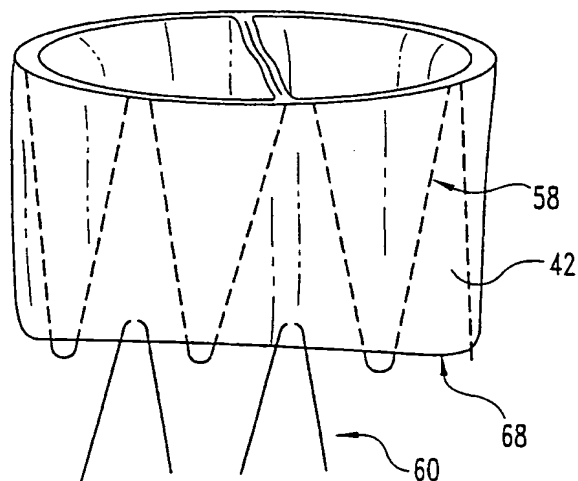


Fig. 13A

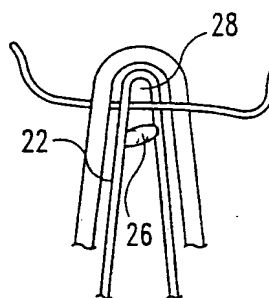


Fig. 13B

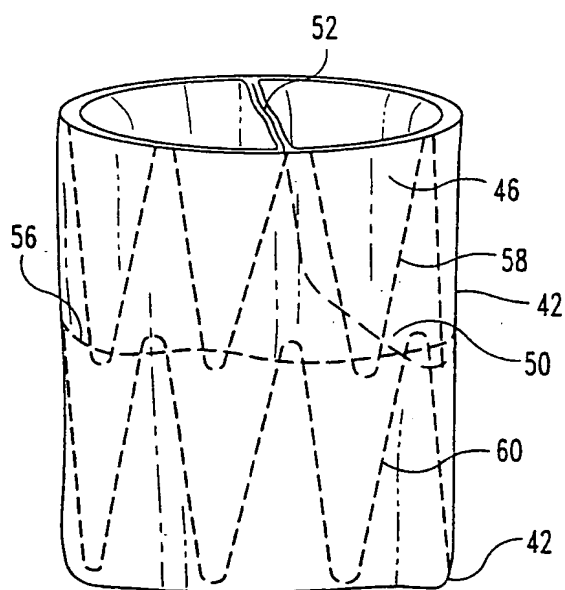


Fig. 14

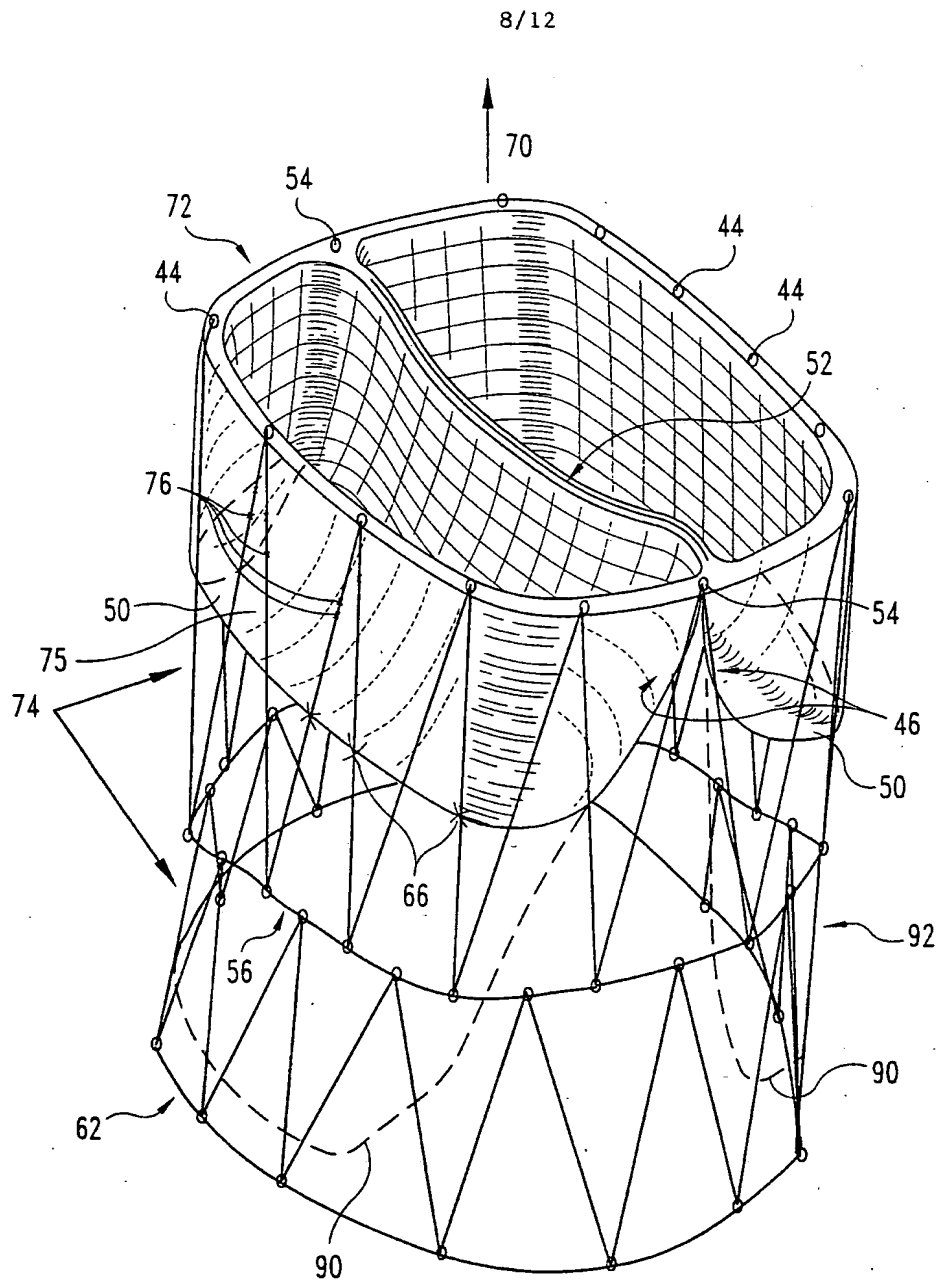


Fig. 15

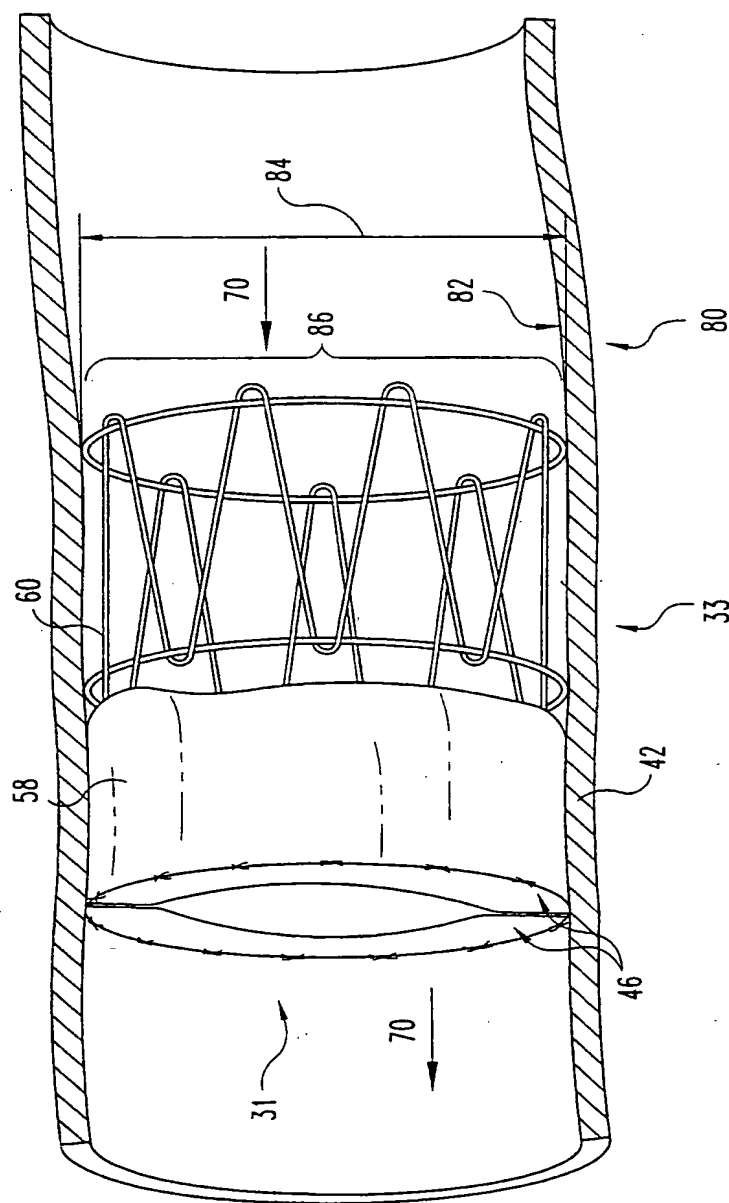


Fig. 16

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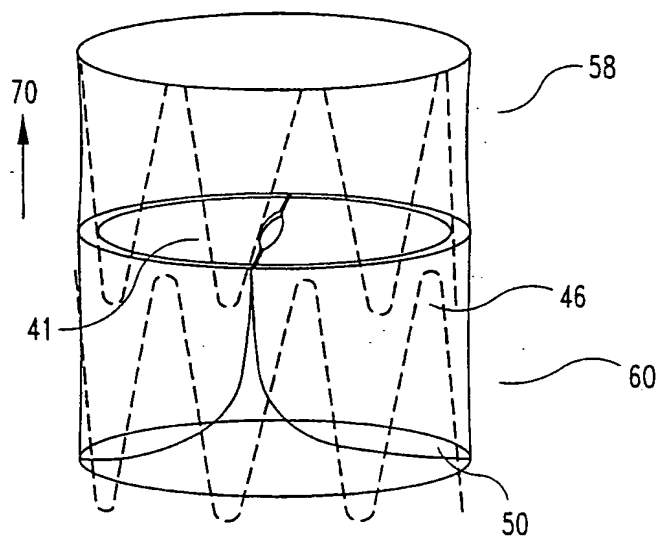


Fig. 17

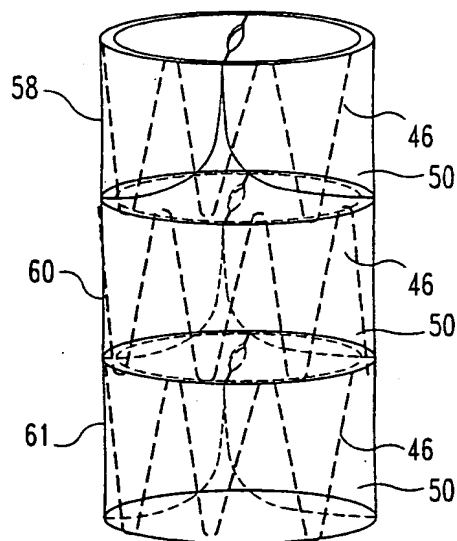


Fig. 18

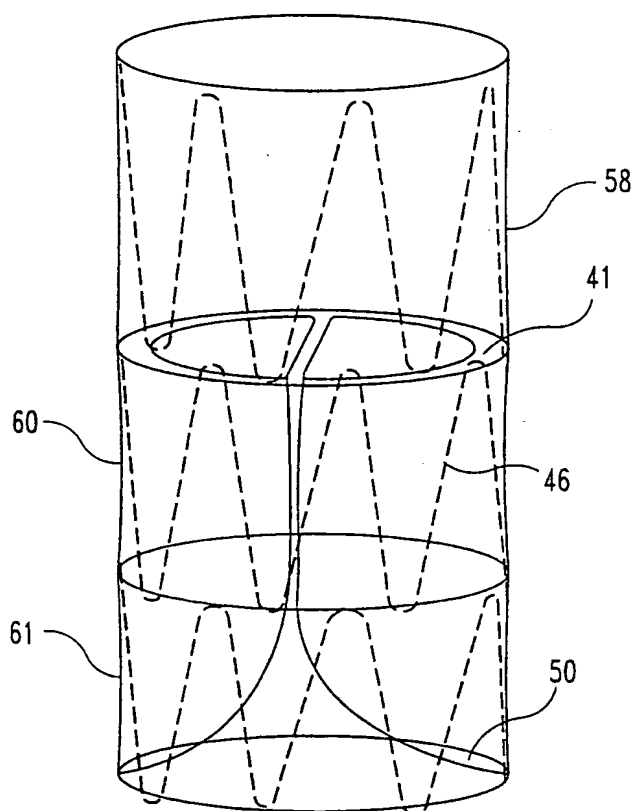


Fig. 19

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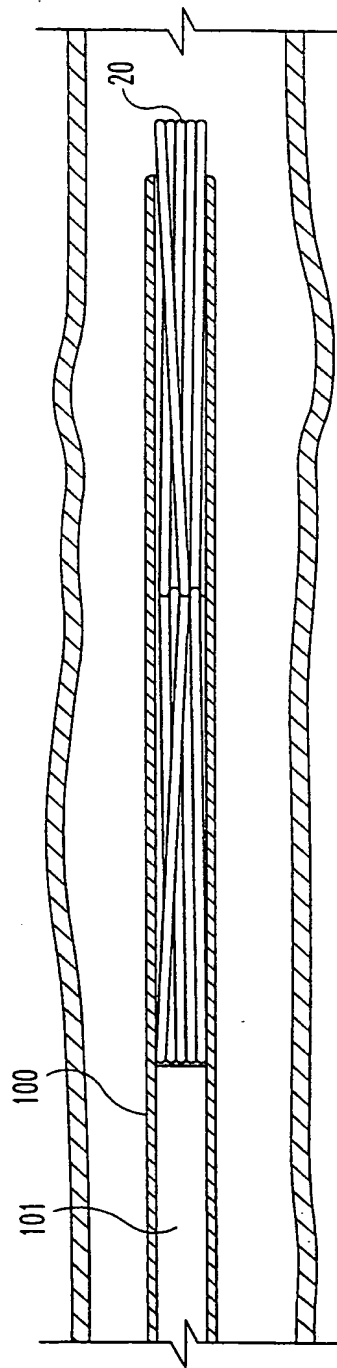


Fig. 20

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/03095

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 808 614 A (SAMSUNG ELECTRONICS CO LTD) 26 November 1997 (1997-11-26)	1-5, 12, 13, 17, 22, 23, 26, 30, 33
A	claims; figures	28, 29, 31, 32
X	US 5 855 601 A (CHUTER TIMOTHY A M ET AL) 5 January 1999 (1999-01-05)	1-5, 12-14, 26, 28, 30-33
A	claims; figures	15, 16, 29

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

28 May 2001

Date of mailing of the international search report

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040. Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Neumann, E

INTERNATIONAL SEARCH REPORT

Int. Application No.

PCT/US 01/03095

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 15224 A (KHOSRAVI FARHAD) 1 April 1999 (1999-04-01)	1,2,5-7, 21,24, 26,28, 30,33
A	page 5, line 23 -page 6, line 11; claims; figures	3,12,31
X	EP 0 850 607 A (CORDIS CORP) 1 July 1998 (1998-07-01)	1,12-14, 23,27,28
A	column 1, line 3 - line 9; figures column 15, line 22 - line 49	29

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ternational Application No

PCT/US 01/03095

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0808614 A	26-11-1997	KR 170220 B KR 170219 B CN 1170612 A JP 10043315 A US 6027525 A	20-03-1999 20-03-1999 21-01-1998 17-02-1998 22-02-2000
US 5855601 A	05-01-1999	NONE	
WO 9915224 A	01-04-1999	US 5925063 A AU 9663298 A US 6221091 B ZA 9808809 A	20-07-1999 12-04-1999 24-04-2001 30-03-1999
EP 0850607 A	01-07-1998	AU 5764998 A WO 9829057 A EP 0967939 A	31-07-1998 09-07-1998 05-01-2000